SUPERIOR COURT OF NEW JERSEY
LAW DIVISION
ATLANTIC COUNTY
CASE NO. 291 CT
MASTER CASE NO. L-6341-10

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IN RE:
PELVIC MESH/GYNECARE
LITIGATION

- - -

CONFIDENTIAL - ATTORNEYS' EYES ONLY
VOLUME II
Friday, November 16, 2012

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Continued oral deposition of DANIEL STEVEN ELLIOTT, M.D., held at MAZIE SLATER KATZ & FREEMAN, L.L.C., 103 Eisenhower Parkway, Roseland, New Jersey, commencing at approximately 8:25 a.m., before Rosemary Locklear, a Registered Professional Reporter, Certified Realtime Reporter, Certified Court Reporter (NJ License No. 30XI00171000), and Notary Public.

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I N D E X

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EXHIBIT INDEX

(Exhibits retained by the court reporter and attached to transcript.)

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I believe you testified yesterday that you've never used or implanted Prolift®; correct?

A. Correct.

Q. Have you ever used or implanted Apogee®?

A. No.

Q. Have you ever used or implanted Perigee®?

A. No.

Q. You never underwent or participated in any of the professional education programs for Prolift®; correct?

A. Correct. I did not.

Q. You never did any cadaver training with respect to Prolift®; correct?

A. I did not.

Q. And you never underwent cadaver training with respect to the use of any mesh products for prolapse repair; correct?

A. No. I'm just trying to remember. In fellowship we may have had cadaver labs on the sacrocolpopexy because our staff was involved in AUA as far as the individual to come in for learning and I may have been

about, the patient-specific issues.

Q. So it's correct, then, that if you can do a transvaginal mesh rescission, you prefer to do so over the transabdominal mesh excision; correct?

A. If it can be safely and successfully accomplished transvaginally, that is, no question, my preferred route.

Q. And that's because transabdominal surgery is a major and morbid surgery; correct?

A. That is fair to say, yes.

Q. Before becoming involved in this litigation, had you ever looked at mesh that had been removed from a patient under a microscope?

A. No.

Q. Have you done that since becoming involved in this litigation?

A. Not of my own patients. I've seen photographs and microscopies and papers.

Q. Prior to being engaged as an expert witness in this matter, had you ever performed any examination of the porosity of

meshes?

A. No.

Q. You don't hold yourself out to be a polymer chemist; correct?

A. That is correct.

Q. If you were counseling a patient on the sacrospinous ligament fixation surgery, what risk would you identify to her with that procedure?

A. Well, I wouldn't have that counsel, consultation because I would send them to my urogynecology colleagues.

Q. Because you don't do sacrospinous ligament fixation procedures; correct?

A. That is correct.

Q. Can you tell me what independent research you did in connection with your role as an expert in this litigation, other than reviewing the materials that plaintiffs' counsel provided to you?

A. Well, I reviewed, as you mentioned, the internal documents, I reviewed roughly, what, 200 manuscripts, scientific journal manuscripts, and then the depositions, which would be the -- from the

litigation.

Q. The internal documents were documents that Mr. Anderson or the other plaintiffs' lawyers gave you; correct?

A. Correct.

Q. Before becoming involved in this litigation, had you ever reviewed any other company's internal documents?

A. Only pertaining to that patent infringement case.

Q. The deposition transcripts, those were given to you by Mr. Anderson or plaintiffs' counsel; correct?

A. Correct. Yes.

Q. The medical literature, the manuscripts that you reviewed, were those given to you by plaintiffs' counsel as well?

A. They gave me a few. So roughly we're looking at 200 or so manuscripts in my report and supplemental report. When this all started, I believe Mr. Anderson gave me 20, maybe 30. So everything else is from me.

Q. So the independent research you did besides reviewing the materials that

plaintiffs' counsel sent to you was you reviewed some of the medical literature and manuscripts.

A. Yeah. It's fair to say that except for what I received from Mr. Anderson and colleagues, everything would be journal reviews.

Q. Do you know any of the study investigators involved in clinical studies concerning Gynemesh® PS?

A. No, I -- I don't know any of those.

Q. Do you know Doug Hale?

A. I don't recognize the name.

Q. Do you know anyone involved in the Prolift® clinical studies?

A. Not that I know of, no.

Q. Now, you've never been employed by the FDA; correct?

A. No.

Q. I'm not correct?

A. No. You are correct. I have never been employed --

MR. ANDERSON: Your bad question.

THE WITNESS: -- or never anticipate being employed by the FDA.

BY MR. SNELL:

Q. Have you ever been a consultant to the FDA?

A. No. The closest would be through that Public Citizen, Ralph Nader's group, where I had comments read at the FDA. But I wouldn't think I would be a consultant for.

Q. Has the FDA ever paid you to be a consultant to provide information to them?

A. No.

Q. Have you ever served on an FDA advisory committee board?

A. No.

Q. Have you ever testified at any government institution, setting aside, you know, the patent case and any other depositions or trial testimony you've given?

A. No.

Q. Have you ever testified at an FDA advisory committee?

A. No. Again, other than that Public Citizen comments. But I was not personally there.

Q. Have you reviewed the federal regulations that pertain to medical devices?

A. No.

Q. Have you ever reviewed any FDA regulations pertaining to devices before becoming engaged as an expert witness in this case?

A. No.

MR. ANDERSON: Off the record.

(Discussion off the record.)

BY MR. SNELL:

Q. Have you ever been involved in the clinical trial designed to evaluate the safety and efficacy of a medical device? When I say clinical trial, I mean in humans.

A. Yes.

Q. What was that?

A. 1998 to '99, it was a new design of an artificial urinary sphincter for men, and I was involved in the original dog studies and then it went into human trials, which my name was on. However, I was not involved because I went down to my fellowship. But my name would be attached to it.

Q. So it's correct that you were not involved in the human clinical trials with regard to this artificial urinary sphincter; correct?

A. I was not involved in the implantation. I was involved heavily as far as the write-up, the documentation. And then timing, I was sent down to my fellowship so I left. I did the work but didn't get to do the surgery.

Q. You've never been involved in a clinical trial designed to evaluate the safety and efficacy of a prolapse device; correct?

A. Correct.

Q. You've never been involved in a clinical trial designed to evaluate the safety and efficacy of a stress urinary incontinence synthetic sling; correct?

A. Correct. I have not.

MR. SNELL: Why don't we take a break.

(Recess, 11:15-11:52 a.m.)

BY MR. SNELL:

Q. Doctor, you've never been

involved in a clinical trial designed to assess the safety and efficacy of a stress urinary incontinence device; correct?

A. Correct.

Q. Prior to becoming involved in this litigation, you had never reviewed a device design safety assessment; correct?

A. From an industry, I guess I don't know -- I just want to make sure I'm clear in understanding your question.

Q. Yes.

A. Would this be an industry --

Q. From a manufacturer, yes.

A. No, I have not.

Q. You're not an FDA regulatory expert, are you?

A. No, I'm not.

Q. Yesterday, Doctor, you mentioned the Iglesia study?

A. Yes.

MR. SNELL: Can we mark it as the next exhibit.

(Exhibit Elliott-9 was marked for identification.)

BY MR. SNELL:

residents, you have to look and feel for the mesh. And many times, it's so encased in scar that you have to go by feel, then you can feel the poking sensation of it. It's sharp.

Q. And in the Prolift® mesh that you have examined, you don't recall it being barbed wire; correct?

A. No. I cannot recall. I did not keep records if it was specifically Prolift®. I do know specifically TVT® but not Prolift®.

Q. Can you tell me any clinical human studies in TVT® that reported a barbed-wire effect with the mesh?

A. I don't recall off the top of my head, no. Barbed wire is a descriptive term, not a scientific term.

MR. SNELL: Okay. Let's have some lunch.

(Luncheon recess, 12:29-1:15 p.m.)

AFTERNOON SESSION

BY MR. SNELL:

Q. Am I correct that you never

looked at any FDA guidance documents before becoming involved in this litigation?

A. I'm not familiar what guidance documents are.

Q. As you sit here today, do you know what FDA guidance documents are?

A. No, I do not.

Q. Do you know whether the mesh that was used in sacrocolpopexies by surgeons between the 1970s and the 1990s, whether that use was cleared by the FDA for use in prolapse?

A. I do not know that.

Q. The FDA has never begun, to your knowledge, any type of enforcement proceedings against Ethicon for the Prolift®; correct?

A. I don't know. Proceedings, again, that falls under regulation territory. I'm a clinician. I know of the only -- the event in I believe 2008 where letters were sent, from what I reviewed in depositions, about not having 510 clearance. But I'm not a regulatory individual.

Q. You're not a regulatory expert on 510(k) clearance.

A. By no means.

Q. And you're not a lawyer; correct?

A. No.

Q. You don't have any legal specialization in what is illegal versus legal conduct; correct?

A. Correct.

Q. I'd like to ask you a couple of questions, Doctor, about Exhibit Number 2.

A. Yes.

Q. And this is your November 7th, 2012, supplemental report; correct?

A. Yes, it is.

MR. SNELL: And, again, for the record, we have filed a Motion to strike this report and identified the bases for that. And I'm not waiving any arguments or rights by questioning the doctor on this report.

BY MR. SNELL:

Q. Doctor, in your November 7th, 2012, report, this is the first time that you identified any opinions with regard to